

CERTIFICATE OF ANALYSIS

PRODUCT : DILTIAZEM HCl (MICRONISED)		COMPENDIA : Ph.Eur.-8.0	
BATCH NO. : DIL/M-01115		QUANTITY : 500 Kg	
MFG. DATE : JANUARY.2015		EXP. DATE : DECEMBER.2019	
QC A.R. No.: FP/018/2015			
TESTS		RESULTS	SPECIFICATIONS
01. CHARACTERS			
i. Appearance		White, crystalline powder.	White or almost white, crystalline powder.
ii. Solubility		Freely soluble in water, in methanol and in methylene chloride, slightly soluble in anhydrous ethanol.	Freely soluble in water, in methanol and in methylene chloride, slightly soluble in anhydrous ethanol.
iii. Melting point		Melted at 213°C with decomposition.	Melts at about 213° C with decomposition.
02. IDENTIFICATION			
IR Absorption		Concordant with working standard	IR Absorption spectrum of the sample is concordant with that of the Diltiazem hydrochloride CRS / working standard.
CHLORIDES		Positive	It gives reaction to chlorides.
03. APPEARANCE OF SOLUTION		Clear and colourless	Clear and colourless.
04. pH		4.7	4.3 to 5.3
05. SPECIFIC OPTICAL ROTATION		+119°	+ 115° to + 120°
06. RELATED SUBSTANCES			
i. Impurity F		Not Quantified	Not more than 0.3% w/w
ii. Unspecified Impurities		Not Quantified	Not more than 0.10% w/w each
iii. Total Impurities		Not Quantified	Not more than 0.30% w/w
07. HEAVY METALS		Less than 10 ppm	Not more than 10 ppm
08. LOSS ON DRYING		0.21%	Not more than 0.50% w/w
09. SULPHATED ASH		0.03%	Not more than 0.10% w/w
10. ASSAY (By Titration)		99.95%	Not less than 98.50% w/w and Not more than 101.00% w/w
(On dried basis)			
ADDITIONAL TEST:			
PARTICLE SIZE			
100%		35 Microns	100% Less than 100 Microns
Surface Area		1.93 m ² /gm	For Information
RESIDUAL SOLVENTS (BY GC-HS)			
Toluene		176 ppm	Not more than 750 ppm
Methanol		132 ppm	Not more than 500 ppm
Isopropyl Alcohol		Not detected	Not more than 1000 ppm
Ethyl Acetate		Not detected	Not more than 500 ppm
Bulk Density		0.28 g/ml	For Information
Tapped Density		0.51 g/ml	For Information

REMARKS: The product conforms to **Ph.Eur.-8.0 & Customer's Specifications**

[Signature]
Prepared by
Executive-QC

[Signature]
Checked by
Manager-QC

[Signature]
Approved by
Manager-QC

Piramal Enterprises Limited

Factory: Digwal Village Kohir Mandal Medak Dist 502321 Andhra Pradesh India

T +91 8451 287508 F +91 8451 287553

Admin. Off: 5-9-30 Road # 4 Basheerbagh Palace Colony Basheerbagh Hyderabad 500 063 India

T +91 40 2322 6719 F +91 40 2326 6041 / 82

Registered Office: Piramal Tower Peninsula Corporate Park Ganpatrao Kadam Marg Lower Parel Mumbai 400 013

T +91 22 3046 6666 F +91 22 2493 6708

W www.piramalhealthcare.com

PIRAMAL ENTERPRISES LIMITED

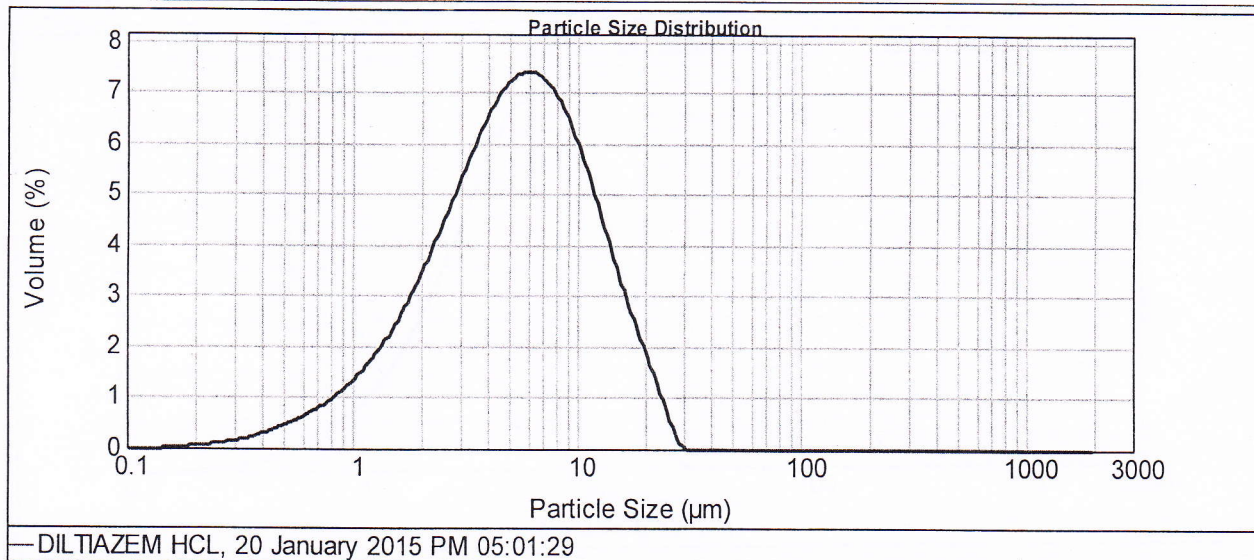
Result Analysis Report

Sample Name: DILTIAZEM HCL
SOP Name: DILTIAZEM HCL
Measured: 20 January 2015 PM 05:01:29
Sample Source & type: Factory = PHL
Measured by: MAHESH
Analysed: 20 January 2015 PM 05:01:30
Sample bulk lot ref: DIL/M-01115(FP-018-2015)
Result Source: Measurement

Particle Name: DILTIAZEM HCL	Accessory Name: Scirocco 2000	Analysis model: General purpose	Sensitivity: Normal
Particle RI: 1.500	Absorption: 0.001	Size range: 0.020 to 2000.000 um	Obscuration: 4.74 %
Dispersant Name:	Dispersant RI: 1.000	Weighted Residual: 0.599 %	Result Emulation: Off

Concentration: 0.0004 %Vol	Span : 2.299	Uniformity: 0.708	Result units: Volume
Specific Surface Area: 1.93 m ² /g	Surface Weighted Mean D[3,2]: 3.110 um	Vol. Weighted Mean D[4,3]: 6.572 um	

d(0.1): 1.530 um d(0.5): 5.245 um d(0.9): 13.587 um



Size (µm)	Vol Under %	Size (µm)	Vol Under %	Size (µm)	Vol Under %	Size (µm)	Vol Under %	Size (µm)	Vol Under %	Size (µm)	Vol Under %
0.017	0.00	2.188	17.16	8.600	73.43	21.000	98.19	130.030	100.00	831.764	100.00
0.026	0.00	2.512	20.87	9.411	77.27	22.000	98.67	149.400	100.00	954.993	100.00
0.158	0.01	2.884	25.16	9.900	79.33	23.000	99.06	150.011	100.00	1096.478	100.00
0.275	0.23	3.311	30.05	10.000	79.73	26.303	99.83	160.000	100.00	1258.925	100.00
0.316	0.36	3.802	35.51	10.200	80.50	34.674	100.00	174.000	100.00	1445.440	100.00
0.363	0.54	4.365	41.47	10.800	82.65	39.005	100.00	181.970	100.00	1659.587	100.00
0.417	0.79	5.012	47.84	11.682	85.40	43.452	100.00	208.930	100.00	1905.461	100.00
0.479	1.12	5.754	54.46	12.475	87.52	45.012	100.00	239.883	100.00	2187.762	100.00
0.631	2.10	6.930	63.45	13.062	88.89	69.824	100.00	275.423	100.00	2511.886	100.00
0.724	2.77	7.390	66.50	13.800	90.42	85.000	100.00	316.228	100.00	2884.032	100.00
0.832	3.59	7.458	66.93	14.465	91.63	97.900	100.00	363.078	100.00	3311.311	100.00
0.955	4.59	7.578	67.68	15.000	92.50	99.850	100.00	416.869	100.00	3801.894	100.00
1.096	5.82	7.874	69.45	15.790	93.64	100.000	100.00	478.630	100.00	5011.872	100.00
1.259	7.32	8.020	70.30	16.308	94.29	119.020	100.00	549.541	100.00	6606.934	100.00
1.660	11.35	8.210	71.36	17.659	95.76	125.000	100.00	630.957	100.00	7585.776	100.00
1.905	14.00	8.500	72.91	18.010	96.08	126.251	100.00	724.436	100.00	10000.000	100.00

Analysed by: *20/01/15*

Checked by: *23/01/15*